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(54) **THERMO-MECHANICALLY CONTROLLED IMPLANTS AND METHODS OF USE**

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(58) **Field of Classification Search**

None

See application file for complete search history.

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(57) **ABSTRACT**

An implant comprises a structure that may be implanted into tissue and that has a first material property at normal body temperature. The first material property is variable at elevated temperatures above normal body temperature. The implant also has a plurality of particles dispersed in the structure that are adapted to convert incident radiation into heat energy when irradiated with electromagnetic radiation. The particles are in thermal contact with the structure such that exposure of the particles to incident radiation raises the temperature of the structure thereby changing the first material property relative to the first material property at normal body temperature.

11 Claims, 11 Drawing Sheets

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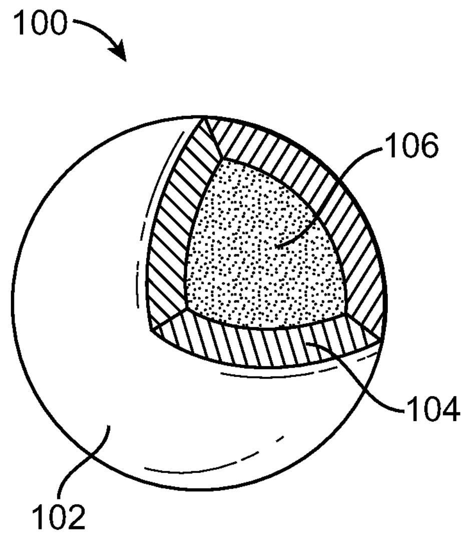

FIG. 1A

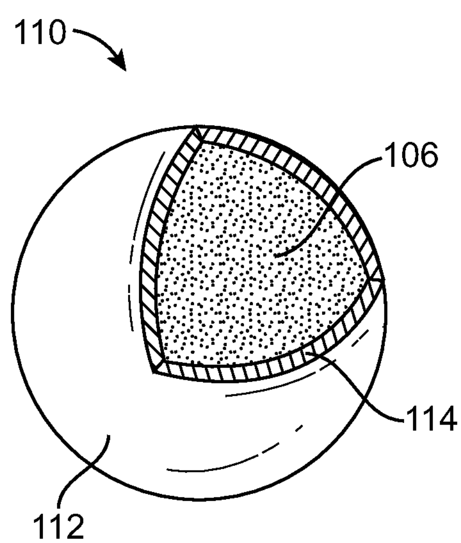

FIG. 1B

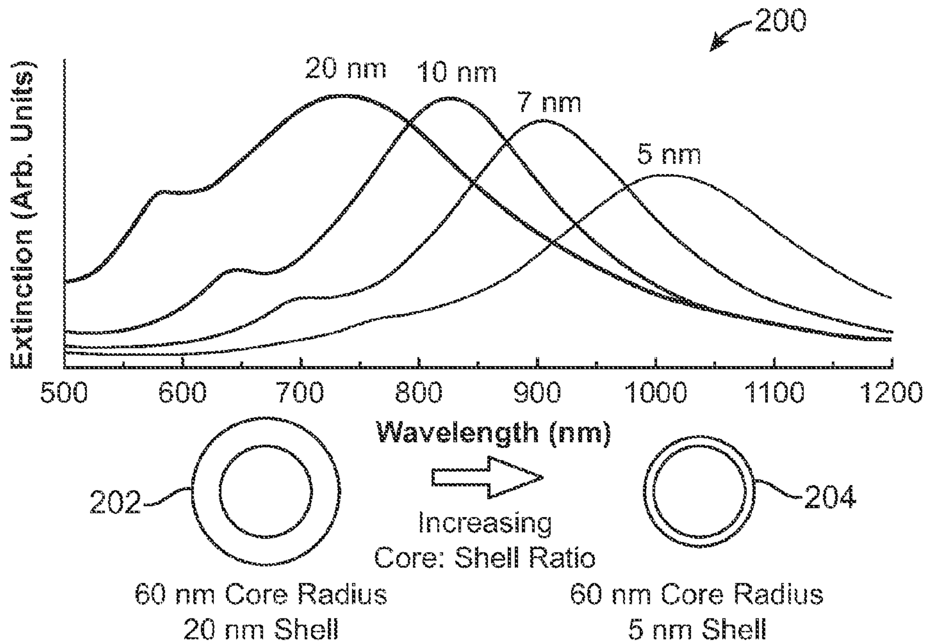

FIG. 2

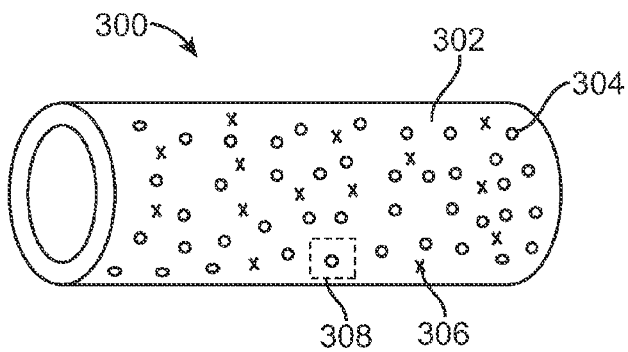

FIG. 3A

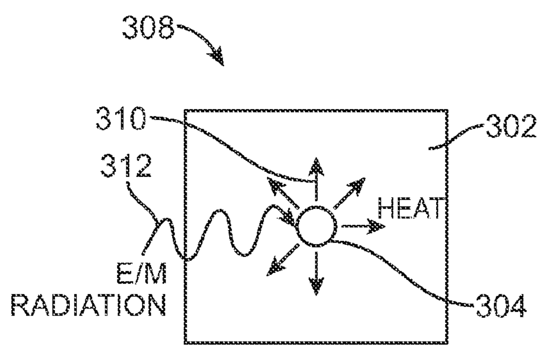

FIG. 3B

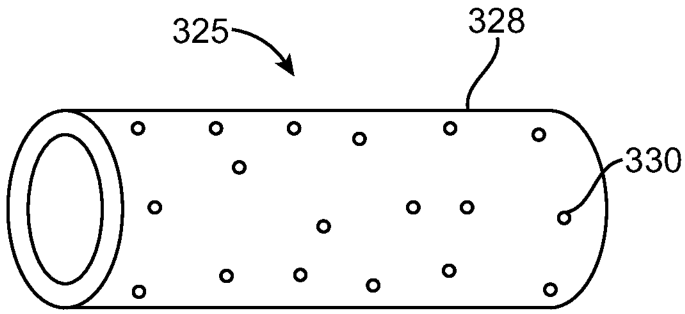

FIG. 3C

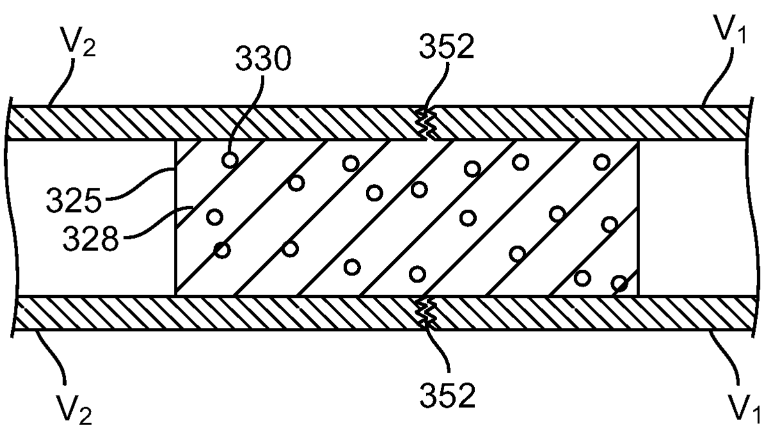

FIG. 3D

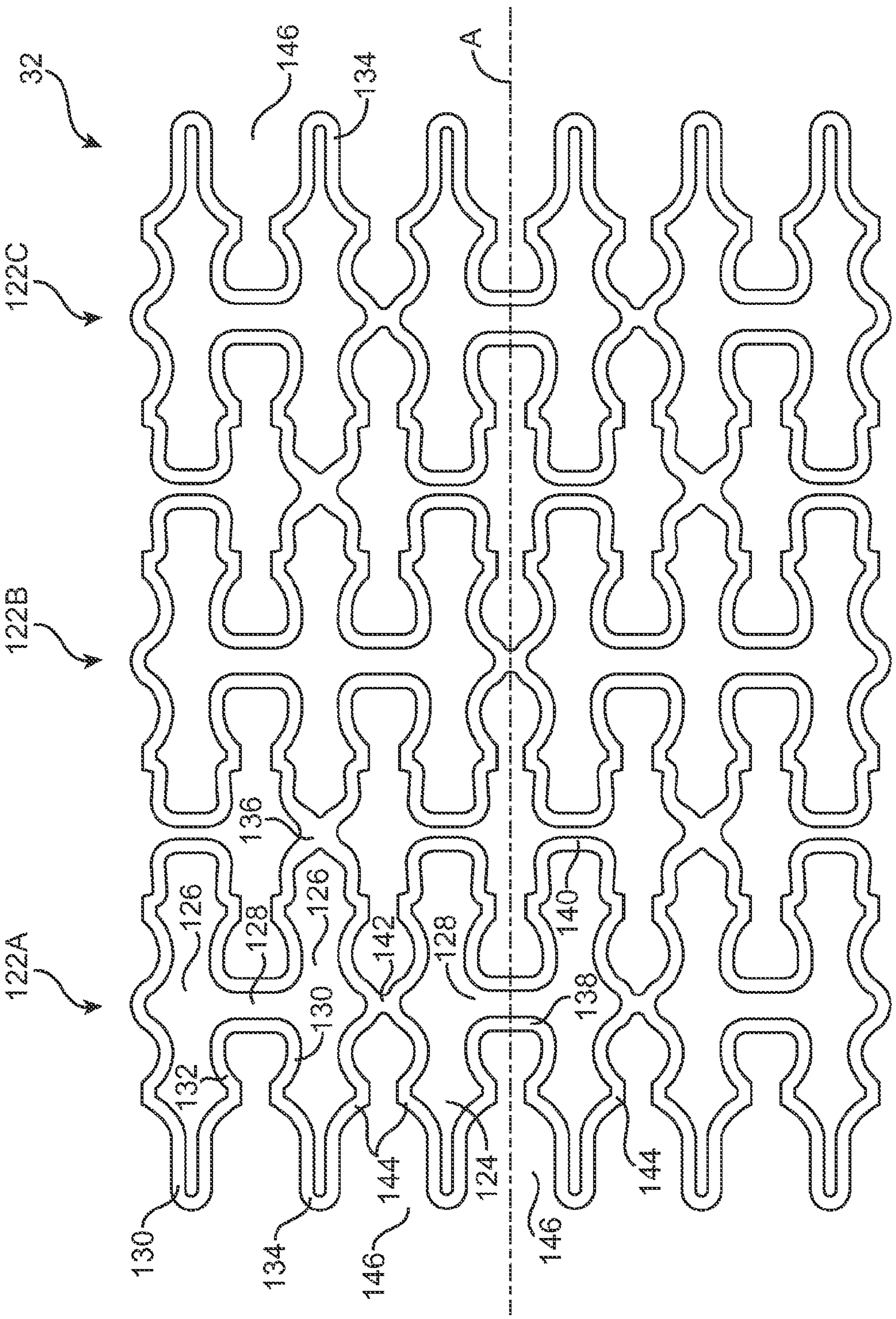
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FIG. 4A

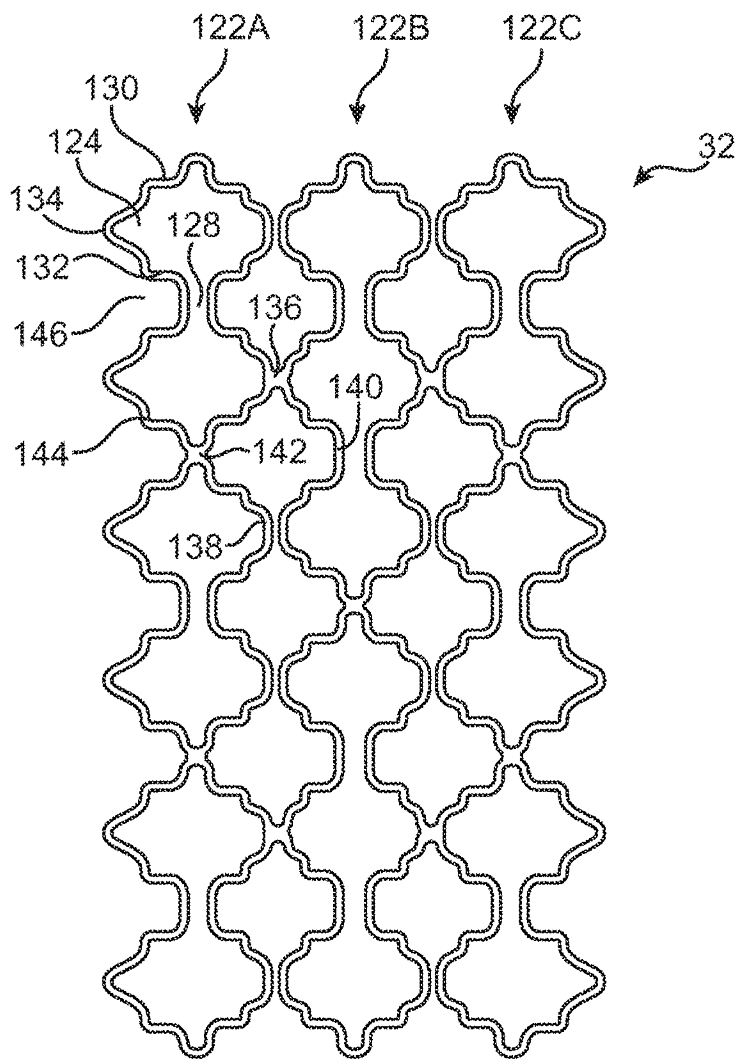

FIG. 4B

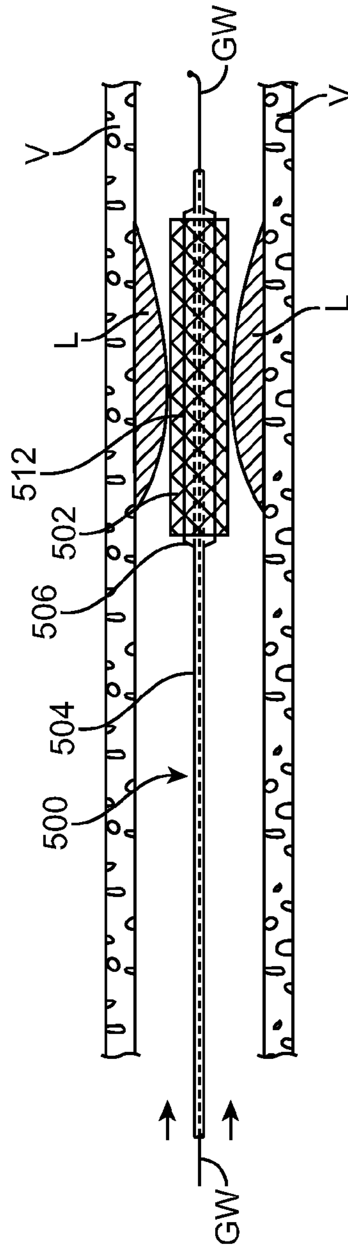
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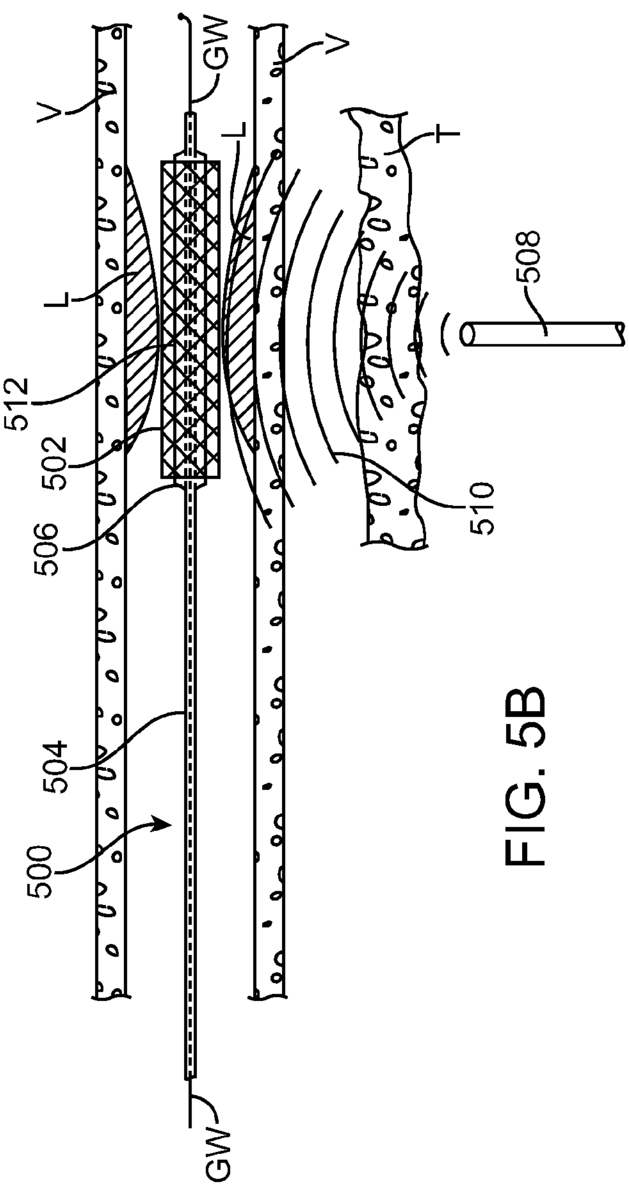
FIG. 5A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506
510
504
500
GW

FIG. 5B

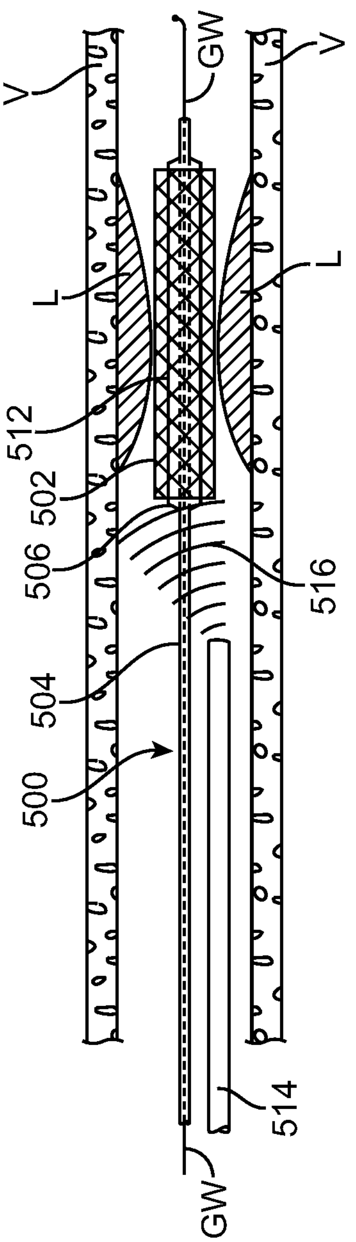
V
GW
V
L
L
512
502
506
516
504
500
514
GW

FIG. 5C

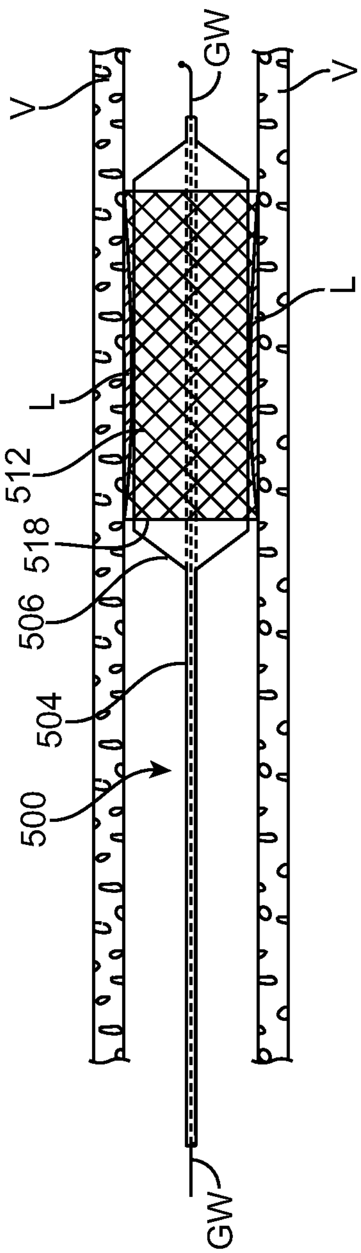
GW
V
V
L
L
512
518
506
504
500
GW

FIG. 5D

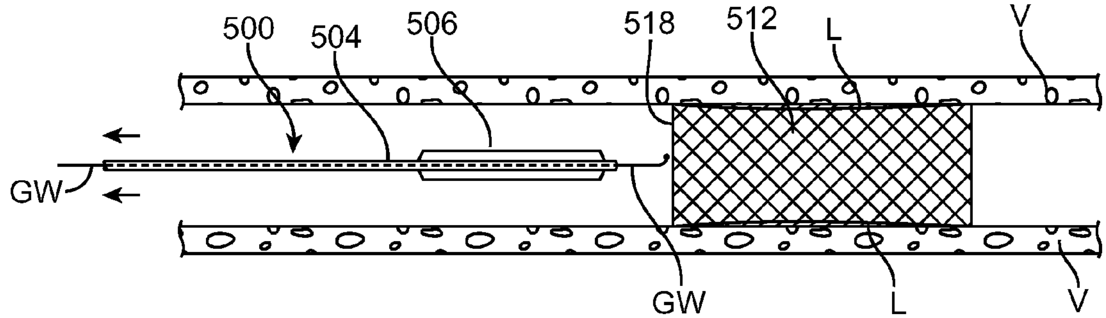

FIG. 5E

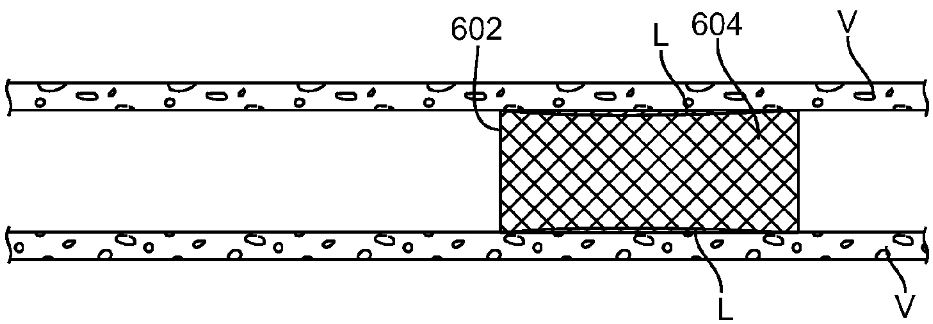

FIG. 6A

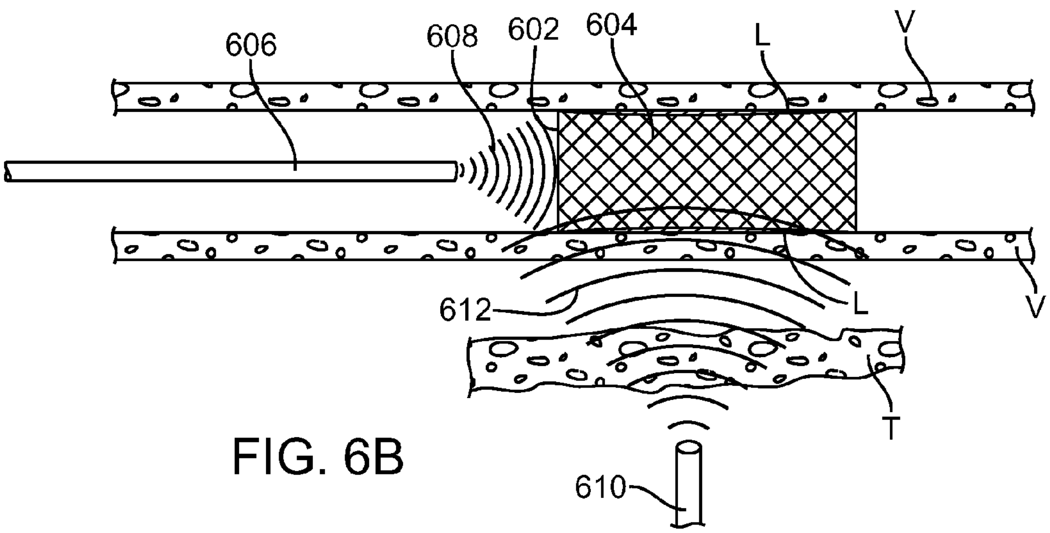

FIG. 6B

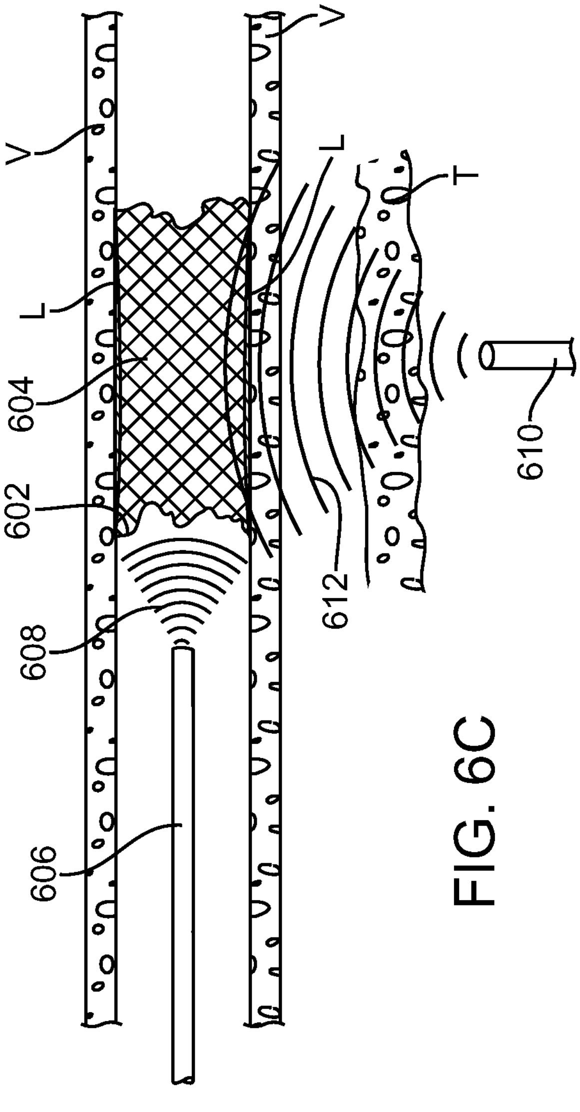

FIG. 6C

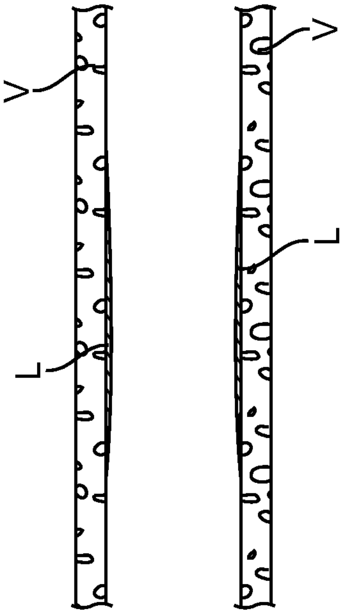

FIG. 6E

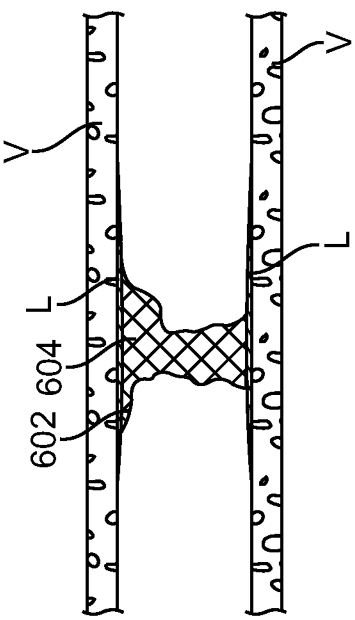

FIG. 6D

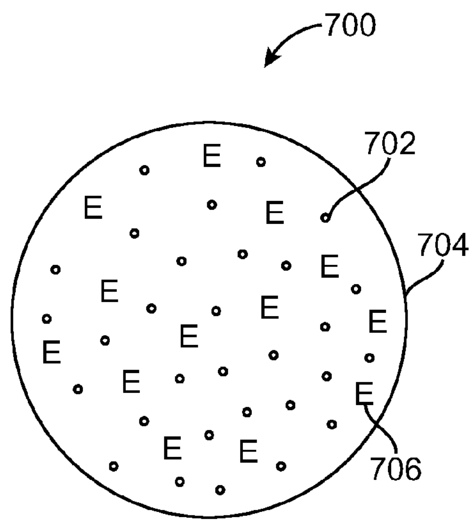

FIG. 7

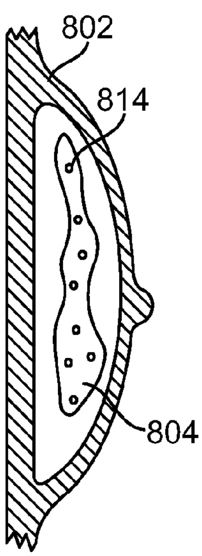

FIG. 8A

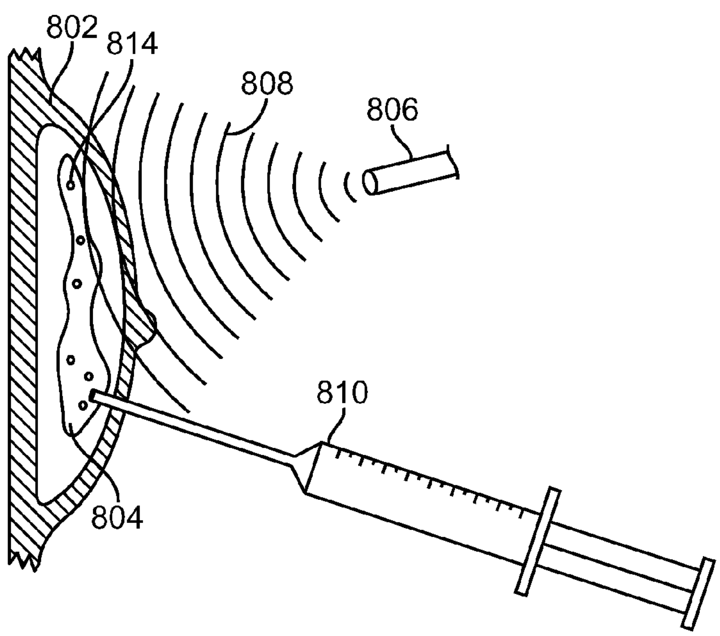

FIG. 8B

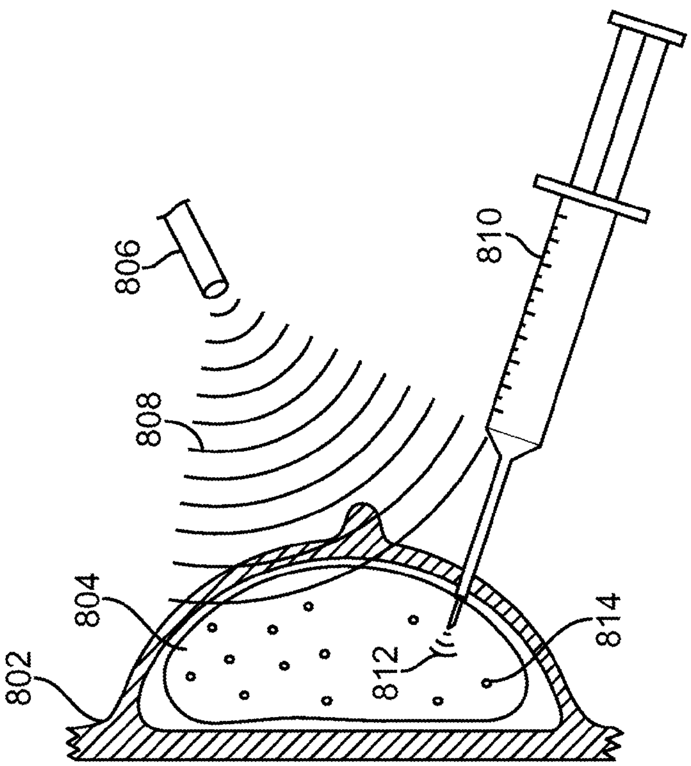

FIG. 8C

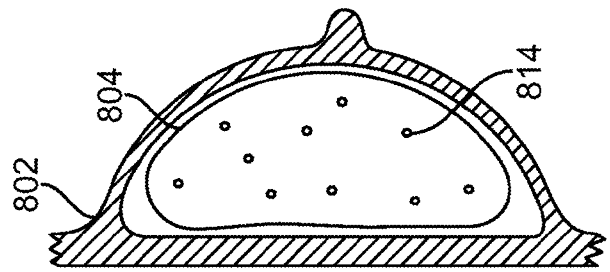

FIG. 8D

THERMO-MECHANICALLY CONTROLLED IMPLANTS AND METHODS OF USE

CROSS-REFERENCES TO RELATED APPLICATIONS

This application is a continuation of U.S. patent application Ser. No. 12/892,553, filed Sep. 28, 2010, which is a continuation of U.S. patent application Ser. No. 12/033,586, filed Feb. 19, 2008, which claims the benefit of U.S. Provisional Application No. 60/890,703, filed Feb. 20, 2007, the full disclosures of which are incorporated herein by reference.

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention relates generally to medical apparatus and methods, and more specifically to implants and biodegradable implants for use in the vascular system as well as other body lumens and cavities.

The use of implants in body tissue is becoming increasingly important in medical treatment. Examples of implant usage include alteration of tissue in cosmetic or reconstructive procedures such as breast augmentation as well as creation, preservation or closure of lumens, channels or fluid reservoirs (e.g. stenting stenotic lesions, exclusion of aneurysms or embolic coils). Implants are also used as matrices for tissue growth (e.g. orthopedic bone fusion procedures), to control unwanted tissue growth and for delivery of therapeutic agents to tissue. Implants may also be employed to join tissue surfaces together or for isolating or protecting tissue lesions in order to enable or mediate healing. Implants are also used to mediate the rate of substances or energy passing into, out of, or through tissue.

Often, implants are fabricated using various metals and/or polymers. Examples of common metals include stainless steel, titanium, nickel-titanium alloys like Nitinol and polymers such as PTFE (e.g. Teflon®), polyethylene, polyurethane and polyester are often used in implants. A potential disadvantage of these permanent implants is that the implant materials may be harder and stiffer than the surrounding tissues, thus anatomical or physiological mismatch may occur, potentially resulting in tissue damage or causing unwanted biological responses. Some materials may fatigue over time and break which can disrupt the layer of endothelial cells potentially causing thrombosis. Additionally, a permanent implant is not always required. An implant may only be required for a limited time period, therefore the implant often must be surgically explanted when it is no longer needed. To overcome some of these challenges, the use of biodegradable polymeric implants has been proposed. Examples of implantable biodegradable polymers include the aliphatic polyester polylactic acid or polylactide (PLA) and polyglycolide (PGA). PGA was originally proposed for use in suture material in the late 1960's. By the early 1970's PLA was proposed as a suture material including both the optically active poly-L-lactide (PLLA) and the racemic mixture poly-DL-lactide (PDLA). PLLA has also been used in biodegradable stents, as reported by Igaki and Tamai. A co-polymer of PLA and PGA, known as PLGA has also been proposed for use in implants. Another material which has recently been proposed (in the 1980's) for use in sutures and orthopedic implants is polydioxanone. In the mid-1990's implantable drug delivery systems using polyanhydrides were proposed by Langer et al. at the Massachusetts Institute of Technology, and more recently tyrosine derived polyarylate has seen use in hernia repair and companies are developing biodegradable stents composed of materials such as a tyrosine derived polycarbonate, poly(DTE carbonate).

While these newer biodegradable implant materials have overcome some of the challenges of earlier implant materials, other potential drawbacks still exist. For example, it is often desirable to adjust the shape of some implants in situ so that the implant conforms more accurately to the anatomy of the treatment site. However, the biodegradable polymers cannot be plastically deformed, molded or shaped at normal body temperatures since they must be solid at body temperature. The implant must therefore be heated above its glass transition temperature, T_g. Often the glass transition temperature is fairly high, for example PDLLA and PLLA have a T_g approximately 50°-80° C., therefore in situ heating may result in localized tissue damage, thrombosis or patient discomfort. It is well known that adding an impurity to a material will change some of the material's properties such as increasing its boiling point and reducing its freezing point. Therefore, additives may be mixed with the biodegradable polymers to decrease the glass transition temperature, for example 2-10% ϵ-caprolactone added to 90-98% PLLA can reduce the glass transition temperature down to about 38°-55° C., but a heat source hotter than the glass transition temperature may still be required due to heat transfer inefficiencies or non-uniform heating, therefore, similar complications may still arise.

One proposed solution to the challenge of non-uniform heating is to coat the implant with a radiation absorbing material which converts radiation to heat. Exemplary coatings include chromophores like indocyanine green, vital blue, carbon black and methylene blue. The radiation, often ultraviolet or visible light must therefore be supplied in situ from a second device due to the poor penetration of the radiation through the tissue. Additionally, production of sufficient and uniform heat using this technique remains a challenge. Furthermore, the chromophores may degrade into unwanted chemicals that are toxic to the body. Therefore, there exists a need for an easier, less toxic and less invasive way to heat implants, including biodegradable polymer implants, to an elevated temperature so that they may be shaped or molded in situ. Furthermore, such techniques should also be able to heat the implant uniformly.

Additionally, while biodegradable implants will degrade over time, it would also be desirable to be able to control the rate of degradation. For example, when an implant is no longer required, it would be desirable to be able to accelerate the degradation rate so that the implant breaks down faster than its normal in situ rate. For this reason, there is also need for a way to control the degradation rate of a biodegradable implant.

2. Description of the Background Art

Prior patents describing nanoshells for converting incident radiation into heat include: U.S. Pat. Nos. 6,344,272; 6,428,811; 6,530,944; 6,645,517; 6,660,381; 6,685,730; 6,699,724; 6,778,316; and 6,852,252. Prior patents describing thermo-mechanically expansion of stents include: U.S. Pat. Nos. 5,670,161; 5,741,323; 6,607,553; 6,736,842. Prior patents describing meltable stents include: U.S. Pat. Nos. 4,690,684 and 4,770,176. Prior patent describing bioerodable polyanhydrides for controlled drug delivery include: U.S. Pat. No. 4,891,225. Prior patents describing tyrosine derived polycarbonate as an implant include: U.S. Pat. Nos. 6,951,053; 7,101,840; and 7,005,454. Prior patents describing biodegradable stents include: U.S. Pat. Nos. 5,733,327; 5,762,625; 5,817,100; 6,045,568; 6,080,177, 6,200,335; 6,413,272; 6,500,204; 6,632,242; RE38,653; RE38,711;

7,066,952; and 7,070,615. The full disclosure of each of these patents is incorporated herein by reference.

BRIEF SUMMARY OF THE INVENTION

The invention generally provides for an implant having a plurality of particles dispersed therein. The particles are adapted to convert incident radiation into heat energy when the particles are irradiated with electromagnetic radiation. The particles are in thermal contact with the implant and therefore the heat generated by the particles raises the temperature of the implant. The increased temperature changes a material property of the implant.

In a first aspect of the present invention, an implant for use in tissue comprises a structure that is adapted for implantation into the tissue and that has a first material property at normal body temperature. The material property is variable at an elevated temperature above normal body temperature. The implant also comprises a plurality of particles that are dispersed in the structure and that are adapted to convert incident radiation into heat energy when the particles are irradiated with electromagnetic radiation. The particles are in thermal contact with the structure and thus exposure of the particles to incident radiation raises the temperature of the structure thereby changing the first material property.

In another aspect of the present invention, an expandable implant for use in tissue comprises a structure that is adapted for implantation into the tissue and that is not plastically deformable at normal body temperature but that is plastically deformable at an elevated temperature above normal body temperature. The implant also has a plurality of particles dispersed in the structure and that are adapted to convert incident radiation into heat energy when irradiated with electromagnetic radiation. The particles are in thermal contact with the structure such that exposure of the particles to the incident radiation raises the temperature of the structure allowing it to be plastically deformed.

In yet another aspect of the present invention, an expandable, biodegradable implant for use in tissue comprises a biodegradable structure that is adapted for implantation into the tissue and that degrades at a first rate when implanted in the tissue at normal body temperature. The implant also comprises a plurality of particles that are dispersed in the structure with the particles adapted to convert incident radiation into heat energy when they are irradiated with electromagnetic radiation. The particles are in thermal contact with the structure such that exposure of the particles to the incident radiation raises the temperature of the structure thereby increasing the degradation rate of the structure relative to the first rate.

The degradation rate of an implant may also be controlled by using an additional reagent such as a catalyst or enzyme. The reagent is adapted to react with the structure so as to increase the structure's degradation rate relative to the first rate at normal body temperature. Often, the reagent is dispersed in a carrier such as a microsphere along with particles such as nanoshells. The microsphere, which may be a hydrogel, is distributed in the implant structure and exposure of the particles to incident radiation raises the temperature of the carrier or microsphere, thereby releasing the reagent.

Often the structure is biodegradable and is composed of a polymer or copolymer, either synthetic or natural, that is not plastically expandable at normal body temperature but is thermo-mechanically expandable at an elevated temperature above normal body temperature. The structure is often composed of one or more of the following materials including, polyhydroxyalkanoates, polyalphahydroxy acids, polysaccharides, proteins, hydrogels, lignin, shellac, natural rubber, polyanhydrides, polyamide esters, polyvinyl esters, polyvinyl alcohols, polyalkylene esters, polyethylene oxide, polyvinylpyrrolidone, polyethylene maleic anhydride and poly(glycerol-sibacate). The structure may also comprise poly-L-lactide, poly-ϵ-caprolactone or a biological fluid in the solid state such as blood plasma. The material property may be the biodegradation rate of the structure, viscosity or the property may be the ability of the structure to be plastically expanded.

Sometimes the structure may be a stent which may be tubular and that is radially expandable at the elevated temperature. The stent may comprise a tube having a sidewall and the sidewall may define a plurality of openings therein. Sometimes the structure may also have a therapeutic agent that is adapted to be released therefrom. The therapeutic agent may be an anti-restenosis agent or it may be at least one of the following, including antibiotics, thrombolytics, anti-thrombotics, anti-inflammatories, cytotoxic agents, anti-proliferative agents, vasodilators, gene therapy agents, radioactive agents, immunosuppressants, chemotherapeutics, endothelial cell attractors, endothelial cell promoters, stem cells and combinations thereof. Sometimes the structure may be adapted to be implanted into a breast or it may be used to deliver a drug to the tissue. The structure may also be used to exclude aneurysms or it may be an orthopedic implant.

The particles may comprise nanoparticles or nanoshells and often the particles have a non-conducting core layer such as silicon dioxide, with a first thickness and a conducting outer shell layer, such as gold, adjacent to the core layer with a second thickness. The ratio of the first thickness to the second thickness defines a maximum wavelength of electromagnetic radiation converted by the particles into heat. Sometimes the particles are substantially spherical. Often the elevated temperature is in the range from about 38° C. to about 60° C. and the electromagnetic radiation often is ultraviolet, visible, near infrared or infrared light.

In another aspect of the present invention, a method of controlling a material property of an implant comprises the steps of providing an implant having a plurality of particles dispersed therein. The implant has a first material property when implanted in tissue at normal body temperature and the material property is variable at an elevated temperature above normal body temperature. Exposing the implant to electromagnetic radiation results in the incident radiation being converted into heat energy thus raising the temperature of the implant above normal body temperature and thereby changing the material property relative to the first material property.

In yet another aspect of the present invention, a method of delivering an expandable implant to a treatment site in a body comprises providing an implant having a plurality of particles dispersed therein and positioning the implant at the treatment site. Positioning may include advancing a catheter through a body lumen with the implant disposed on the catheter. Exposing the implant to electromagnetic radiation allows the particles to convert the incident radiation into heat energy. The heat energy raises the implant temperature above its glass transition temperature such that the implant may be plastically deformed so as to change its shape. Expanding the implant may include expanding a balloon.

In another aspect of the present invention, a method of controlling the degradation rate of an implant comprises providing a biodegradable implant having a plurality of particles dispersed therein. The implant degrades at a first rate when implanted in tissue at normal body temperature. Exposing the implant to electromagnetic radiation allows the particles to convert the incident radiation into heat energy which raises the temperature of the implant above normal body temperature. The elevated temperature changes the biodegradation rate of the implant relative to the first rate. Exposing the implant may include irradiating a carrier such as a microsphere, dispersed in the implant and containing a reagent and particles. The carrier heats up and releases the reagent when irradiated and the reagent reacts with the implant to degrade it. The reagent may be an enzyme or catalyst.

The method may also comprise discontinuing exposure of the implant to the electromagnetic radiation in order to allow the implant to cool down so that it returns to body temperature so that the implant is substantially undeformable plastically at body temperature. The method may also include monitoring the temperature of implant. Exposing the implant to electromagnetic radiation may include exposing the implant from outside the body or from within the body. Sometimes a catheter may be used to deliver the radiation to the implant. The radiation may be delivered for a fixed duration of time, continuously for a defined period or over periodic intervals until a desired temperature obtained in the implant.

These and other embodiments are described in further detail in the following description related to the appended drawing figures.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGS. **1**A-**1**B show nanoshells having various outer shell thicknesses.

FIG. **2** illustrates the optical resonances of metal nanoshells having various ratios of core radius to shell thickness.

FIG. **3**A shows a biodegradable stent having nanoshells dispersed therein.

FIG. **3**B shows a nanoshell generating heat in a section of the stent shown in FIG. **3**A.

FIG. **3**C shows an implant made from frozen biological fluid and having nanoshells dispersed therein.

FIG. **3**D shows the implant of FIG. **3**C used to facilitate creation of an anastomosis.

FIGS. **4**A-**4**B illustrate a preferred embodiment of a stent in the unexpanded and expanded state.

FIGS. **5**A-**5**E illustrate stent expansion in accordance with an exemplary embodiment.

FIGS. **6**A-**6**E illustrate stent biodegradation in accordance with an exemplary embodiment.

FIG. **7** illustrates a microsphere containing nanoshells and a chemical reagent dispersed therein.

FIGS. **8**A-**8**D illustrate expansion of a breast implant in accordance with an exemplary embodiment.

DETAILED DESCRIPTION OF THE INVENTION

FIGS. **1**A and **1**B illustrate nanoshells having various outer shell thicknesses. Nanoshells are nanoparticles having a diameter ranging from a few nanometers up to about 5 microns. The nanoshells are composed of a non-conducting, semiconductor or dielectric inner core layer and an ultra thin conducting outer shell layer. In the exemplary embodiment of FIG. **1**A, nanoshell **100** is spherically shaped and has an outer spherical shell **102** made from gold. A portion **104** of outer shell **102** has been removed in FIG. **1**A so that the inner spherical core **106** is visible. Inner core **106** is made from silicon dioxide. Other common materials that may be utilized for the inner core include, but are not limited to, gold sulfide, titanium dioxide, polymethyl methacrylate, polystyrene and macromolecules such as dendrimers. Metals which are well suited for use in the outer shell also include, but are not limited to silver, copper, platinum, palladium, lead, iron and the like. Nanoshells may be made with various inner core diameters and outer shell thicknesses. FIG. **1**B illustrates another nanoshell **110** having a thinner outer shell **112** compared with the outer shell **102** of FIG. **1**A. The nanoshell in FIG. **1**B also has a section **114** of outer shell **112** removed so that the inner core **106** is visible.

Nanoshells have a unique ability to interact with specific wavelengths of electromagnetic radiation and effectively convert the incident radiation into heat energy. By adjusting the relative core and shell thicknesses, and choice of materials, nanoshells can be fabricated that will react with or scatter light at any wavelength across much of the ultraviolet, visible and infrared range of the electromagnetic spectrum. The nanoshell may therefore be tuned to specific wavelengths of electromagnetic radiation and the conversion of incident radiation to heat energy can be optimized.

FIG. **2** shows a graph **200** of the optical resonances of metal nanoshells having various ratios of core radius to shell thickness. In FIG. **2**, nanoshells **202** and **204** both have a 60 nm inner core made from silicon dioxide. Nanoshell **202** has a gold outer shell, 20 nm thick and the resulting maximum absorption wavelength is approximately 740 nm. As the shell thickness decreases, the maximum absorption wavelength increases. Nanoshell **204** has a gold shell layer 5 nm thick and the resulting maximum absorption wavelength is approximately 1010 nm. The tunability of nanoshells, including the relationship between the ratio of core diameter to shell thickness and maximum absorption wavelength is more fully discussed in U.S. Pat. No. 6,344,272 which has previously been incorporated herein by reference.

Nanoshells are well described in the scientific and patent literature. Other aspects of nanoshells such as manufacturing methods, materials and principles of operation are described in U.S. Pat. Nos. 6,428,811; 6,530,944; 6,645,517; 6,660,381; 6,685,730; 6,699,724; 6,778,316; and 6,852,252, the entire contents of which have previously been incorporated herein by reference.

Because nanoshells are efficient at converting incident radiation into heat, they may be dispersed in implants and light or other forms of electromagnetic radiation may be used to heat up the implant. Furthermore, since a nanoshell may be tuned to certain wavelengths, a nanoshell that preferentially interacts with light at near infrared wavelengths between approximately 700 and approximately 2500 nm is desirable, and more preferably between about 800 nm and 1200 nm, since this range of wavelengths is transmitted through tissue with very little absorption and therefore relatively little attenuation. Thus the majority of the light is delivered to the nanoparticles, converted into heat and transferred to the implant in which the nanoparticles are dispersed. This makes external access to an implanted device possible and heating of the tissue surrounding the implant is substantially avoided. One particular source of near infrared light, a Nd:YAG laser emits light at a wavelength of 1064 nm and hence is ideal for irradiating an implant from outside the body. Additionally, in the case of a biodegradable implant, as the implant breaks down the nanoshells are released into surrounding tissue. Due to their small size, the nanoshells are easily purged by body systems such as the kidneys. Nanoshells therefore present a unique way of allowing an implant to be heated from outside the body with minimal biocompatibility issues.

FIG. **3**A shows an implantable stent **300**. Stents are defined to include any of the array of expandable prostheses and scaffolds which are introduced into a lumen at a target treatment site and expanded in situ thereby exerting a radially outward force against the lumen wall to restore patency. Stents may be implanted in a number of lumens including the coronary and peripheral vasculature, biliary ducts, urethra and ureter, as well as other body cavities. Urethral and ureter stents are well reported in the patent literature, including for example U.S. Pat. Nos. 7,112,226 and 7,044,981, the entire contents of which are incorporated herein by reference. Other stents are discussed and incorporated below. Stent **300** is a tubular prosthesis made from any material **302** that is solid at normal body temperature and that may be plastically deformed at an elevated temperature. Examples include standard engineering thermoplastics such as polyurethane and others well known to those skilled in the art, including biodegradable polymers like polylactide. Stent **300** may optionally be a copolymer containing 2-10% of poly-ϵ-caprolactone so as to adjust the mechanical properties of the stent, including lowering the glass transition temperature to just above normal body temperature. In preferred embodiments, the copolymer stent **300** has a glass transition temperature in the range from about 40° to about 60° C. Stent **300** may also comprise plasticizers to further soften the implant. The plasticizers should be biocompatible such as oleic acid and linoleic acid which are classified under Food and Drug Administration (FDA) guidelines for food additives as being Generally Recognized as Safe (GRAS). The stent **300** may be delivered to the site of a stenotic lesion or an intimal dissection and expanded in situ in order to restore patency of a vessel.

In FIG. **3**A, preferably 0.0001 to 1% nanoparticles **304**, more preferably 0.00025% to 0.5%, and most preferably 0.0005% to 0.1% nanoparticles are dispersed in the stent **300**. The nanoparticles **304** may be tuned to interact with many forms of electromagnetic radiation including microwaves, ultrasound, magnetic fields, electric fields, radiofrequency, infrared, visible, ultraviolet, laser, x-rays, gamma rays and cosmic rays. However, in this exemplary embodiment, the nanoparticles **304** are preferably tuned to interact with near infrared radiation having a wavelength approximately 1064 nm so that that a Nd:YAG laser may be used to irradiate stent **300** from outside the body. The nanoparticles **304** in this embodiment are preferably nanoshells having an outer shell composed of gold and an inner core composed of silicon dioxide. The nanoparticles **304** convert the incident radiation into heat, thereby heating the polymer matrix above its glass transition temperature and allowing stent **300** to be plastically deformed into a lesion with a balloon or other expandable member in situ. Optionally, stent **300** may also include quantum dots dispersed therein. Quantum dots have many desirable characteristics, including favorable optical properties. The quantum dots may be used to help visualize stent **300** while in situ since they fluoresce when irradiated with certain wavelengths of light. Examples of materials used to fabricate quantum dots include cadmium selenide, cadmium sulfide, zinc sulfide and zinc selenide.

FIG. **3**B illustrates a section **308** of FIG. **3**A which has been enlarged to show how incident radiation **312** interacts with nanoparticle **304** such that the radiation **312** is converted into heat by nanoparticle **304** and the heat **310** is emitted to the surrounding polymer matrix **302**. In this exemplary embodiment, stent **300** is a tubular prosthesis without any apertures in the sidewalls and therefore it could also be used to exclude an aneurysm. However, this is not meant to be limiting and stent **300** may be modified to include apertures in the sidewalls.

In many of the embodiments described herein, near infrared light is used to irradiate the nanoparticles and generate heat. However, it should be obvious to one of ordinary skill in the art that many wavelengths of electromagnetic radiation may also be used, including a magnetic field. The nanoparticles may be magnetically responsive so that they produce heat upon exposure to a magnetic field. Examples of magnetically responsive materials include iron oxides, magnetite (Fe_3O_4) and maghemite (γ-Fe_3O_3).

FIGS. **4**A and **4**B illustrate a preferred embodiment of one possible stent geometry. In FIG. **4**A a portion of stent segment **32** is shown in a planar shape for clarity. Stent segment **32** comprises parallel rows **122**A, **122**B and **122**C of I-shaped cells **124** formed into a cylindrical shape around axial axis A. Cells **124** have upper and lower axial slots **126** and a connecting circumferential slot **128**. Upper and lower slots **126** are bounded by upper axial struts **132**, lower axial struts **130**, curved outer ends **134**, and curved inner ends **136**. Circumferential slots **128** are bounded by outer circumferential strut **138** and inner circumferential strut **140**. Each I-shaped cell **124** is connected to the adjacent I-shaped cell **124** in the same row **122** by a circumferential connecting strut **142**. Row **122**A is connected to row **122**B by the merger or joining of curved inner ends **136** of at least one of upper and lower slots **126** in each cell **124**.

In FIGS. **4**A-**4**B, the stent includes a bulge **144** in upper and lower axial struts **130**, **132** extending circumferentially outwardly from axial slots **126**. These give axial slots **126** an arrowhead or cross shape at their inner and outer ends. The bulge **144** in each upper axial strut **130** extends toward the bulge **144** in a lower axial strut **132** in the same cell **124** or in an adjacent cell **124**, thus creating a concave abutment **146** in the space between each axial slot **126**. Concave abutments **146** are configured to receive and engage curved outer ends **134** of cells **124** in the adjacent stent segment, thereby maintaining spacing between the stent segments. The axial location of bulges **144** along upper and lower axial struts **130**, **132** may be selected to provide the desired degree of inter-segment spacing.

FIG. **4**B shows a stent **32** of FIG. **4**A in an expanded condition. It may be seen that axial slots **124** are deformed into a circumferentially widened modified diamond shape with bulges **144** on the now diagonal upper and lower axial struts **130**, **132**. Circumferential slots **128** are generally the same size and shape as in the unexpanded configuration. Bulges **144** have been pulled away from each other to some extent, but still provide a concave abutment **146** to maintain a minimum degree of spacing between adjacent stent segments. As in the earlier embodiment, some axial shortening of each segment occurs upon expansion and stent geometry can be optimized to provide the ideal intersegment spacing.

It should also be noted that the embodiment of FIGS. **4**A-**4**B also enables access to vessel side branches blocked by stent segment **32**. Should such side branch access be desired, a dilatation catheter may be inserted into circumferential slot **128** and expanded to provide an enlarged opening through which a side branch may be entered.

A number of other stent geometries are applicable and have been reported in the scientific and patent literature. Other stent geometries include, but are not limited to those disclosed in the following U.S. Patents, the full disclosures of which are incorporated herein by reference: U.S. Pat. Nos. 6,315,794; 5,980,552; 5,836,964; 5,527,354; 5,421,955; 4,886,062; and 4,776,337.

Referring back to FIG. **3**A, stent **300** may also comprise a therapeutic agent **306**. In preferred embodiments, stent **300** may be coated, impregnated, infused or otherwise coupled with one or more drugs that inhibit restenosis, such as Rapamycin, Everolimus, Biolimus A9, Paclitaxel, prodrugs, or derivatives of the aforementioned, or other suitable agents, preferably carried in a durable or bioerodable carrier of polymeric or other suitable material. Alternatively, stent **300** may be coated with other types of drugs or therapeutic materials such as antibiotics, thrombolytics, anti-thrombotics, anti-inflammatories, cytotoxic agents, anti-proliferative agents, vasodilators, gene therapy agents, radioactive agents, immunosuppressants, chemotherapeutics, endothelial cell attractors or promoters and/or stem cells. Such materials may be coated over all or a portion of the surface of stent **300**, or stent **300** may have a porous structure or include apertures, holes, channels, or other features in which such materials may be deposited.

FIG. **3**C illustrates an implant where nanoshells may be used to control the degradation of the implant. In an exemplary embodiment, a stent **325** is adapted for creating an anastomosis. The stent **325** may be made from a variety of meltable materials including polymers, frozen blood plasma or other biological fluids in the solid state. Nanoshells **330** are dispersed in the stent **325**. FIG. **3**D shows the stent **325** placed into the ends V**1**, V**2** of the two vessels to be connected together, thereby aligning the ends together so that they may be sutured or thermally bonded together, creating an anastomosis **352**. In this embodiment, after the stent **325** has been placed into the vessel ends, V**1**, V**2**, and the ends have been connected together, stent **325** may be irradiated with near infrared light from outside the body. The nanoshells **330** convert the incident radiation into heat. The resulting heat melts the stent **325** thereby creating a patent lumen for fluid flow. Further details on meltable stents are disclosed in U.S. Pat. Nos. 4,690,684 and 4,770,176, the entire contents of which are fully incorporated herein by reference.

Referring now to FIGS. **5**A-**5**E, the deployment of a stent to treat a stenotic lesion is shown in accordance with an exemplary embodiment. While the embodiment will be described in the context of a femoral artery stent procedure, it should be understood that the invention may be employed in any variety of coronary or peripheral arteries, blood vessels and other body lumens in which stents or tubular prostheses are deployed, including the carotid and iliac arteries, blood vessels in the brain, other arteries or veins, as well as non-vascular body lumens such as the ureter, urethra, fallopian tubes, the hepatic and biliary duct and the like. In FIG. **5**A, a stent delivery catheter **500** includes a stent **502** having a plurality of nanoshells **512** dispersed therein and mounted over an expandable balloon **506** attached to the distal end of catheter shaft **504**. In this exemplary embodiment, a single biodegradable stent **502** is disposed on the delivery catheter **500**, although multiple stents may also be disposed on the delivery catheter **500**. Stent **502** is preferably composed of a copolymer containing approximately 90 to 99% polylactide with 1 to 10% poly-ϵ-caprolactone, and more preferably 95 to 99% polylactide with 1 to 5% poly-ϵ-caprolactone, uniformly blended with preferably 0.0001 to 1% gold nanoshells, more preferably 0.00025% to 0.5%, and most preferably 0.0005% to 0.1% gold nanoshells that are tuned to convert near infrared light into heat. Stent **502** may also be fabricated from any material that is solid at normal body temperature and that can be plastically deformed at an elevated temperature, thus many other polymers such as polyurethanes as well as other biodegradable materials may be used to fabricate the stent **502**. Delivery catheters such as over-the-wire systems and rapid exchange systems are well known in the art and may be used to deliver stent **502** to the lesion L.

Having multiple stents allows the physician operator to select the number of stents to deliver and thus customization of stent length is possible, as disclosed in U.S. Patent Publication Nos. 2006/0282150 and 2007/0027521, the entire contents of which are incorporated herein by reference. Additionally, other customizable-length stent delivery systems have been proposed for delivering multiple stent segments and these may also be used to deliver one or more stents **502**. Prior publications describing catheters for delivering multiple segmented stents include: U.S. Pat. Nos. 7,309,350; 7,326,236; 7,137,993; and 7,182,779; U.S. Patent Publication Nos. 2005/0038505; 2004/0186551; and 2003/0135266. Prior related U.S. Patent Applications, Publications and Provisionals include Ser. Nos. 2006/0282150; 2006/0282147; 2007/0179587; 2007/0067012; 60/784,309; and Ser. No. 11/462,951. The full disclosures of each of these patents and applications are incorporated herein by reference.

In. FIG. **5**A, the delivery catheter **500** is introduced into a treatment vessel first, by placing an introducer sheath (not illustrated) into the target peripheral artery, typically using a percutaneous procedure such as the Seldinger technique or by surgical cutdown. In this exemplary embodiment, the target vessel is a femoral artery. The introducer sheath is then advanced slightly into the femoral artery. A guidewire GW is then inserted through the introducer and advanced into the target vessel V where a lesion L to be treated is located. The proximal end of guidewire GW is then inserted through the distal end of catheter shaft **504**, through a lumen in catheter shaft **504**, exiting at the proximal end of catheter shaft **504**, which is outside the patient's body.

Stent delivery catheter **500** is then slidably advanced over the guidewire GW into the vessel V so that stent **502** traverses the lesion L. Optional radiopaque markers (not illustrated) may be placed on the catheter shaft **504** in order to facilitate visualization of the delivery catheter under fluoroscopy. Once the delivery catheter has been properly positioned in the vessel, the stent **502** may be heated up to facilitate its expansion.

In FIG. **5**B, an external source of electromagnetic radiation **508** is used to irradiate stent **502** so as to heat it up. In FIG. **5**B, the external source of radiation is preferably a Nd:YAG laser which emits a wavelength of light approximately 1064 nm. This wavelength is applied extracorporally and the light **510** is transmitted through the tissue T to the stent **502**. Nanoshells **512** dispersed in the stent **502** are tuned to convert the light into heat. Heat generated by nanoshells **512** is transferred to the polymer which makes up stent **502**, thereby heating it up. In addition or as an alternative to applying extracorporeal radiation, radiation may be applied in situ. FIG. **5**C shows a fiber optic catheter **514** deployed alongside delivery catheter **500**. The fiber optic catheter **514** is adapted to deliver the Nd:YAG laser light **516** directly to stent **502**. In some embodiments, the delivery catheter **500** and the fiber optic catheter **514** may be combined into a single device that heats and deploys stent **502**. In some embodiments, fiber optic catheter **514** includes an optional diffuser (not shown). The diffuser is adapted to spread out and scatter the radiation so as to cover a larger area of the stent **502**.

Radiation is applied until the temperature of stent **502** is above its glass transition temperature, T_g, which is approximately 40°-60° C. in this exemplary embodiment. The exposure time is dependent upon many factors, including but not limited to, area of radiation coverage, wavelength and intensity of the radiation, type and mass of the implant material and nanoshell concentration. Therefore, exposure time could range from a few seconds to a few hours, and more preferably from about 10 seconds to about an hour. Longer exposure times are not desirable due to patient inconvenience.

Stent **502** is fabricated from a material having a glass transition temperature above normal body temperature. Therefore, stent **502** is solid at or below normal body temperature. Normal body temperature is approximately 37° C., therefore the stent **502** material is selected to have a T_g slightly higher than 37° C., yet not so high that the temperature required to heat the stent above T_g results in tissue damage.

Once the temperature of stent **502** is raised above the glass transition temperature, it's viscosity decreases, permitting stent **502** to be plastically deformed. In FIG. **5**D, balloon **506** is expanded, typically with contrast media and/or saline and an inflation device such an Indeflator™, manufactured by Abbott (formerly Guidant Corp., Santa Clara, Calif.). Stent **502** is soft and therefore expands with balloon **506** to an expanded state **518**, covering lesion L. After stent **502** has been enlarged to its expanded state **518**, application of radiation may be discontinued, allowing stent **518** to cool down to body temperature. When stent **518** cools down, it solidifies and permanently retains its expanded shape. In FIG. **5**E, balloon **506** is then deflated and delivery catheter **500** is withdrawn from the vessel, leaving stent **518** with nanoshells **512** in place. Stent **518** is composed of biodegradable materials and therefore, over time will degrade, releasing nanoshells **512** into the vascular system where they will be filtered and purged out of the body by the kidneys.

Referring now to FIGS. **8**A-**8**D, the expansion of an implant for breast augmentation during cosmetic and reconstructive procedures (e.g. after mastectomy) is shown in accordance with an exemplary embodiment. In FIG. **8**A, an implant **804** having nanoparticles **814** dispersed therein is implanted using standard surgical or minimally invasive techniques into a breast **802**. The implant may be any biocompatible thermoplastic or material that is solid at normal body temperature and that may be plastically deformed upon heating. Examples of such materials include, but are not limited to polyurethanes, polyethylene, and PVC. Nanoparticles **814** may be tuned to convert any wavelength of electromagnetic radiation into heat, however, in this exemplary embodiment, nanoparticles **814** are tuned to near infrared light, such as that provided by a Nd:YAG laser.

In FIG. **8**B, the breast **802** is irradiated with near infrared light **808** from an Nd:YAG laser **806**. As previously discussed, this wavelength of light is easily transmitted through tissue without being attenuated. The light **808** therefore irradiates the nanoparticles **814**, here preferably nanoshells having a gold outer shell and a silicon dioxide inner core, such that the incident radiation is converted into heat. The heat raises the temperature of implant **802** above its glass transition temperature, lowering its viscosity and softening the implant **802**. A syringe **810** may then be used to fill the implant **804** with a fluid such as saline in order to expand the implant to a larger volume as seen in FIG. **8**C. Once the breast **802** has been enlarged to a desired size and/or shape, irradiation **808** may be suspended allowing the implant **804** to cool down and solidify and permanently retain the expanded shape. Syringe **810** may then be removed as shown in FIG. **8**D. In alternative embodiments, other expandable members, such as a balloon catheter could be used to expand the implant. Additionally, repeat treatments may be applied as required in order to fine tune the implant to obtain a more desirable clinical result, or to accommodate changes in breast size or shape that occur with aging. Similar implants may also be used in other areas of the body, such as for shaping the chin, nose, lips, face, buttocks, calf, legs, thighs, legs, or any part of the body.

Nanoshells may also be used to control the degradation rate of a biodegradable implant. FIGS. **6**A-**6**E illustrate a method of controlling the degradation rate of a biodegradable implant by using nanoshells to heat up the implant, thereby accelerating the rate at which the implant degrades in situ. In this exemplary embodiment, degradation of a stent is described. However, this is not meant to be limiting, as biodegradation of a number of other implants may be controlled in a similar manner. For example, ureteral implants, ocular implants or drug delivery devices (e.g. for treatment of cancer or diabetes), need only be implanted for a limited time, therefore it is desirable to be able to accelerate their degradation so as to avoid having to surgically remove them. In FIG. **6**A, a stent **602** has been expanded and implanted at the site of a stenotic lesion L in a vessel V. The vessel may be a coronary artery, a peripheral artery or any body lumen or cavity. Stent **602** is composed of a biodegradable polymer having a plurality of nanoshells **604** dispersed therein. In this exemplary embodiment, stent **602** is preferably composed of a copolymer having approximately 90 to 99% polylactide and 1 to 10% poly-ϵ-caprolactone, and more preferably 95 to 99% polylactide and 1 to 5% poly-ϵ-caprolactone, uniformly blended with 0.0001 to 1%, more preferably 0.00025% to 0.5% and most preferably 0.0005% to 0.1% gold nanoshells that are tuned to convert near infrared light having a wavelength in the range from about 700 nm to about 2500 nm, and more preferably between about 800 nm and 1200 nm into heat. Other biodegradable polymers and nanoshells are possible, and this exemplary embodiment is not intended to be limiting.

Some examples of other biodegradable materials include polyesters such as polyhydroxyalkanoates (PHA) and polyalphahydroxy acids (AHA). Exemplary PHAs include, but are not limited to polymers of 3-hydroxypropionate, 3-hydroxybutyrate, 3-hydroxyvalerate, 3-hydroxycaproate, 3-hydroxyheptanoate, 3-hydroxyoctanoate, 3-hydroxynonanoate, 3-hydroxydecanoate, 3-hydroxyundecanoate, 3-hydroxydodecanoate, 4-hydroxybutyrate and 5-hydroxyvalerate. Examples of AHAs include, but are not limited to various forms of polylactide or polylactic acid including PLA, PLLA or PDLLA, polyglycolic acid and polyglycolide, poly(lactic-co-glycolic acid), poly(lactide-co-glycolide), poly(ϵ-caprolactone) and polydioxanone. Polysaccharides including starch, glycogen, cellulose and chitin may also be used as a biodegradable material. It is also feasible that proteins such as zein, resilin, collagen, gelatin, casein, silk or wool could be used as a biodegradable implant material. Still other materials such as hydrogels including poly(hydroxyethyl methylacrylate), polyethylene glycol, poly(N-isopropylacrylamide), poly(N-vinyl-2-pyrrolidone), cellulose polyvinyl alcohol, silicone hydrogels, polyacrylamides, and polyacrylic acid are potential biodegradable implant materials. Other potential biodegradable materials include lignin, shellac, natural rubber, polyanhydrides, polyamide esters, polyvinyl esters, polyvinyl alcohol, polyalkylene esters, polyethylene oxide, polyvinylpyrrolidone, polyethylene maleic anhydride and poly(glycerol-sibacate). Still another potential biodegradable material include the polyphosphazenes developed by Harry R. Allcock at Pennsylvania State University.

In FIG. **6**B, a Nd:YAG laser **610** is used to extracorporally irradiate stent **602** with near infrared light **612**. Light **612** supplied from laser **610** is at a wavelength approximately 1064 nm which can pass through tissues T without being significantly absorbed. The light **612** irradiates stent **602** and nanoshells **604** dispersed in the stent **602** interact with the light **612** and convert it into heat which raises the temperature of stent **602**. Optionally, as an alternative or supplement to light **612** from laser **610**, a fiber optic catheter **606** may be advanced to the site of the stent **602** using standard catheter delivery techniques and near infrared light **608** from a Nd:YAG laser may be intravascularly delivered to stent **602** to further irradiate stent **602**. The exposure time is dependent upon many factors, including but not limited to, area of radiation coverage, wavelength and intensity of the radiation, type and mass of biodegradable material, nanoshell concentration, and concentration of any catalysts or enzymes in the implant. Therefore, exposure time could range from a few seconds to a few hours, and more preferably from about 10 seconds to about an hour. Exposure times greater than an hour, such as those seen in phototherapy regimes used to treat neonatal jaundice or in Crigler-Najjar syndrome (e.g. 12 hours/day) become impractical due to patient inconvenience. Stent **602** is irradiated to a temperature above the glass transition temperature, which as described above is selected to be slightly higher than normal body temperature and low enough to minimize potential tissue thermal damage.

As stent **602** temperature increases, naturally occurring chemical reactions between the body and the stent **602** are accelerated, thereby increasing the rate at which stent **602** breaks down. In FIG. **6**C, stent **602** has partially degraded. Continued irradiation of stent **602** with near infrared light **608** and **612** maintains the stent **602** at an elevated temperature and the stent continues to break down as shown in FIG. **6**D. This process continues until the entire stent **602** has degraded into low molecular weight, non-toxic products and therefore is removed from lesion L, as shown in FIG. **6**E. Nanoshells **604** in the stent **602** are released into the vascular system during degradation and they are small enough to be filtered out of the body by the kidneys.

In alternative embodiments, a microsphere containing nanoshells and a chemical reagent may be dispersed in the implant and used to accelerate biodegradation even more than previously described. FIG. **7** illustrates a microsphere **700**, having a diameter approximately in the range of 1-10 μm and made from a hydrogel **704** such as polyvinyl alcohol, sodium polyacrylate, acrylate polymers and copolymers having an abundance of hydrophilic groups. Other hydrogels have been previously discussed. Nanoshells **702** are dispersed within the microsphere **700** along with a chemical reagent **706**. The reagent may be any substance which reacts with an implant to degrade it. Examples of possible reagents include, but are not limited to hydrolases that catalyze hyrolysis of various bonds, lyases that cleave various bonds by means other than hydrolysis or oxidation and oxidases that cause oxidation. The use of these reagents can accelerate the rate of biodegradation relative to the method described above with respect to FIGS. **6**A-**6**E. When the microsphere **700** is irradiated, the nanoshells **702** convert the incident radiation into heat thereby raising the temperature of microsphere **700**. As described previously, the irradiation time is dependent upon many factors, including but not limited to, area of radiation coverage, intensity of the radiation, type and mass of biodegradable polymer, nanoshell concentration, hydrogel water concentration, and concentration of any catalysts or enzymes in the implant. Therefore, exposure time could range from a few seconds to a few hours, and more preferably from about 10 seconds to about an hour. In some embodiments, it may be desirable to spread the implant irradiation over multiple sessions, such a weekly, monthly or daily either for patient convenience or to control the bioerosion process.

As the microsphere **700** is irradiated and heats up, it expands and releases the reagent E into the implant material. The reagent begins to chemically react with the implant material, breaking it down, thus accelerating the in situ biodegradation rate. Additional information on methods of use, materials and principles of operation of controlled drug delivery systems are reported in the scientific and patent literature including U.S. Pat. No. 6,645,517 (West et al.) and U.S. Pat. No. 4,891,225 (Langer et al.), the entire contents of which are incorporated herein by reference. In other embodiments, an implant having different layers of degradable materials could be independently degraded by selectively releasing various reagents E from the microsphere **700** at different temperatures. The various layers could be bioeroded away at the same time during a single treatment session, or the layers may be selectively bioeroded away with multiple exposures to electromagnetic radiation at different times.

While the exemplary embodiments have been described in some details for clarity of understanding and by way of example, a variety of additional modifications, adaptations and changes may be clear to those of skill in the art. Hence, the scope of the present invention is limited solely by the appended claims.

What is claimed is:

1. A polymeric orthopedic implant for use in tissue where the implant comprises a polymer having a plurality of metallic nanoshells dispersed within the polymer, wherein the nanoshells are covered with a metal selected from the group consisting of: palladium, silver, platinum, and gold, and wherein the polymer has a glass transition temperature of between 38° and 60° C. and a first material property when implanted in tissue at normal body temperature, the material property being variable at an elevated temperature above the glass transition temperature when the implant is exposed to electromagnetic radiation in the range of about 800 nm to 1200 nm, the radiation being converted into heat energy via the plurality of nanoshells thus uniformly raising the temperature of the polymer above the glass transition temperature, and thereby changing the material property relative to the first material property where the material property is at least one of:

(i) the ability of the implant to be plastically deformed such that the implant is not plastically deformable at normal body temperatures but is plastically deformable at an elevated temperature above normal body temperature or

(ii) the viscosity of the implant where the implant has a lower viscosity at an elevated temperature above normal body temperature or

(iii) the biodegradation rate of the implant where the polymer of the implant is biodegradable.

2. The implant of claim **1** wherein the nanoshells are covered with gold.

3. The implant of claim **1** wherein the polymer further comprises a microsphere carrier containing a reagent which is released upon exposure to radiation.

4. The implant of claim **3** wherein the reagent reacts with the implant to degrade it.

5. The implant of claim **3** wherein the reagent is an enzyme.

6. The implant of claim **1** wherein the polymer is a standard engineering plastic.

7. The implant of claim **1** wherein the polymer is selected from the group consisting of polyhydroxyalkanoates and polyalphahydroxy acids.

8. The implant of claim **1** wherein the polymer is biodegradable.

9. The implant of claim **1** wherein the polymer is selected from the group consisting of polymers of 3-hydroxypropionate, 3-hydroxybutyrate, 3-hydroxyvalerate, 3-hydroxycaproate, 3-hydroxyheptanoate, 3-hydroxyoctanoate, 3-hydroxynonanoate, 3-hydroxydecanoate, 3-hydroxyundecanoate, 3-hydroxydodecanoate, 4-hydroxybutyrate and 5-hydroxyvalerate.

10. The implant of claim **1** wherein the polymer is selected from the group consisting of monomers of polylactide, polyglycolide, poly(lactide-co-glycolide), poly(ϵ-caprolactone) and polydioxanone.

11. A polymeric orthopedic implant for use in tissue where the implant comprises a polymer having a plurality of metallic nanoshells dispersed within the polymer, wherein the nanoshells are covered with a metal selected from the group consisting of: palladium, silver, platinum, and gold,

and wherein the polymer has a glass transition temperature of between 40° and 60° C. and a first material property when implanted in tissue at normal body temperature, the material property being variable at an elevated temperature above the glass transition temperature when the implant is exposed to electromagnetic radiation in the range of about 800 nm to 1200 nm, the radiation being converted into heat energy via the plurality of nanoshells thus uniformly raising the temperature of the polymer above the glass transition temperature, and thereby changing the material property relative to the first material property where the material property is at least one of:

(i) the ability of the implant to be plastically deformed such that the implant is not plastically deformable at normal body temperatures but is plastically deformable at an elevated temperature above normal body temperature or

(ii) the viscosity of the implant where the implant has a lower viscosity at an elevated temperature above normal body temperature or

(iii) the biodegradation rate of the implant where the polymer of the implant is biodegradable.

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